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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,731	05/17/2006	Kazumichi Uotani	0171-1273PUS1	8869

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
12/05/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/579,731	UOTANI ET AL.	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The present application has been transferred to the present Examiner by former Examiner Young. Due to the recitation of new art, the present application is being sent Non-Final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over M.R. Johnson (US 2003/0195160 A1) in view of Tanimoto et al. (US 5,447,732) and Yalpani (US 20040063612) (former two discussed in previous action).

It is noted that claim 1 is now closed-ended (consisting of), while all the remaining claims remain open (comprising).

Johnson, as noted in previous Examiner's action, teaches a compound that is a sodium channel blocker directed, among other purposes, to modulating sodium channels so as to allow

proper moisturizing or wetting of mucosal surfaces (paragraphs [0004-0005], page 1), reciting xerostomia in particular (paragraph [0011], page 2) as one particular problem related to lack of surface liquid and that one object of his invention is to provide a method of treating dry mouth xerostomia comprising administering to the mouth of the subject the compound of his invention (paragraphs [0092-0093], page 4), which can be formulated as a salt of organic acids such as polyglutamic acid (paragraph [0162], bottom right-hand column of page 5, the recitation of polyglutamic acid itself being in the first line of the left-hand column of page 6). The method of treating dry mouth (xerostomia) by administering the compound (or its salt) is claimed in claim 65, left-hand column, page 22. It can be appreciated that although Johnson does not claim polyglutamic acid in his claim regarding his method of treating xerostomia, his inclusion of polyglutamic acid in a list of art-recognized pharmaceutical salt components teaches the use of polyglutamic acid or its salt form, polyglutamate, as part of a treatment for xerostomia. It being in the nature of salts to readily dissociate into their component species it can be further appreciated that polyglutamate ion would thus be able to exert any expectorant or sialogenic effect in may possess. Johnson's method of administering the active salts is not claimed but is suitable to the location being treated, as per the mouth if necessary.; similarly Johnson's claims are directed to "an effective amount" of his compound without any limitation as to the range of concentrations embodied. It should be noted that M. R. Johnson has a similar invention, disclosed in US Patent Application Publication 2003/0199456 A1,
published October 23, 2003 (also filed February 19, 2002), relating to a similar sodium-channel blocker, formulated similarly, to be used in methods of treating similar mucosal hydration conditions, including xerostomia, as above.

Tanimoto et al teach a composition containing poly-glutamic acid and its degradation products that will act as a mineral-absorption enhancer when used in foods, in a variety of forms, including beverages, gels, solids or powders. Tanimoto et al. also teach that poly-glutamic acid is naturally available in a non-isolated product of the bacterium *Bacillus natto,* and that the advantage of Tanimoto et al. invention is that poly-glutamic acid can be provided as a source of nutrition, in pure form, with less cost and labor (column 3, lines 52-68). Tanimoto et al also teach that poly-glutamic acid and its sodium or other salts can be used interchangeably (column 4, lines 60-62) and that it can be readily used as or in food (column 4, lines 63-69, carried over to column 5, lines 1-52). In this regard Tanimoto et al further provide a recipe for beef curry in which sodium poly-?-glutamate is used as an ingredient (column 10, Example 10, lines 34-56, carried over to lines 1-15 of column 11. More food recipes incorporating sodium poly-glutamate are provided throughout the remainder of columns 11, 12, and 13. Tanimoto et al claim compositions comprising 0.1-10% w/w poly-glutamate in claim 1 and similarly, with a concentration of 0.01-5% w/w in their claim 2, this broad range anticipating the instant claim 5 by overlap. It can be appreciated that the incorporation of poly-glutamate into food items it can be consumed from one to as many times per day as desired or required, thus anticipating the instant claim 6. Tanimoto et al's claims 5-13 claim use of their composition comprising poly-glutamate in a range of food types (liquid, Solid or powder) and foodstuffs. The methods of providing the poly-glutamate composition to mammals are claimed in claims 14 and 15.

Yalpani et al. teach PGA or polyglutamic alone:

[0054] These in homogeneities and structural variabilities of chemically derived poly(amino acids) are reflected in the study of Hefti et al. cited above. The authors attempted to examine a number of poly(amino acids) derived by thermal polycondensation of amino acid precursors and their ability to stimulate growth of dissociated fetal rat forebrain neurons (Hefti, F., et al., Brain Res., 541, 273-83, 1991). The authors studied either commercial homopolymers, e.g., .alpha.-polyglutamic acid with average molecular weights of up to 43,000 Da (from Sigma Chemical Co.) or copolymers (with Mw of 1,000-10,000 Da) containing multiple amino acid repeat units, e.g., aspartic acid, glutamic acid and tryptophan. The authors were unable to correlate the observed activities to polymer structures. They acknowledged substantial compositional heterogeneities of the polymers, such as the presence pigments and significant amounts of non-peptide linkages. They noted significant inconsistencies in the performance of these materials as a given poly(amino acid) could display variable potencies and be active or inactive, depending on the conditions of its preparations. Similarly, a poly(tryptophan) was inactive, whereas a copolymer of tryptophan and aspartic acid exhibited potency. The authors postulated that the presence of dicarboxylic acids was a prerequisite for activity. Hefti et al. also acknowledged close similarities in the activity of serum alone to those of their polymers.

Yalpani also teach in para 61, that such products may be administered orally.

As noted in the previous application:

In the instant case, Johnson, in paragraph [0162], pages 7-8, lists compounds that are suitable for preparing salts of his active ingredient for a preparation directed towards alleviating xerostomia. Johnson's active ingredient, a sodium channel blocker, acts on ion channels and can be administered in its pure form or conjugated and organic acid and presented to the subject as a salt. One suitable organic acid stated by Johnson is polyglutamic acid (page 8, left-hand column, line 1). Polyglutamic acid is a member of a list of incidental ingredients of Johnson's invention and it would be obvious to select through the list and use polyglutamic acid in a formulation to be used for the same intended result, namely, improved flow of saliva and alleviation of xerostomia.

Thus, Johnson teach that compositions for treating dry mouth or xerostomia also comprising PGA were known in the art. And it is known that PGA used in range amounts of 10,000+ (Daltons) is also known, as Yalpani teaches, and in the 0.1 to 10% by weight of composition amount, as Tanimoto et al. teaches. Thus, all the elements of the claimed invention are known (the addition of such known additives as saccharin, etc. merely be known oral-based additions routinely selected and provided no unobvious advancement, e.g. Applicant's claims 2-3). So, the issue is why does the combination of the above render either a closed-ended (e.g. Applicant's claim 1) or open-ended (Applicant's claim 2) PGA composition obvious, that may be used for any oral product (under a products broadest reasonable interpretation, e.g. Applicant's claims 1-3 and 7-10) or in a method of treating xerostomia? Because of Applicant's current choice of transition phrases: the method claims leave e.g. Applicant's product claims 2-3 and 7-10, as well as method claims 4-6 open to PGA WITH ANYTHING ELSE for treating xerostomia (e.g. Johnson ref.). Similarly, Yalpani teach that PGA is known to be used alone in certain products (those tested in Yalpani (e.g. para 54) and administered orally (para 61); thus nothing would prevent the Yalpani product from being used alone, in an oral product, especially since an amino acid which are well known to be ingested orally (irrespective of what call (sialogogue, oral composition, food product, toothpaste, gum)).

For the reasons set forth above, and the combination of references herein, the products and method remain obvious.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In e.g. claim 1, it is unclear what is meant by the phrase "having an average molecular weight of 10,000 to 5,000,000"? What is the measurement, e.g. Daltons?

In e.g. claim 5, it is unclear what is meant by the phrase "is 0.001 to 10% by weight"? Against what other amount/measurement, total composition? E.g. 10% by weight of total composition weight?

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maury Audet/
Examiner, Art Unit 1654